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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,452	06/14/2006	Andreas Lendlein	Q116797	3000

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
MCEVOY, THOMAS M	

ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
03/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/560,452	LENDLEIN ET AL.	
	Examiner	Art Unit	
	THOMAS MCEVOY	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,17-30,32,35,38-40 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,17-30,32,35,38-40 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 31st 2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 3, 4, 17-30, 32, 35, 38-40 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fine et al. (US 5,800,516) in view of Langer et al. (US

6,388,043) or alternately, Fine et al. (US 5,800,516) in view of Langer et al. (US 6,388,043) and Dickson (US 2004/0034405).

Regarding claim 32, Fine et al. disclose: a method of treatment of a patient needing a stent comprising the steps of: (a) placing a stent 10 onto a balloon catheter (col. 3, lines 26-30). Fine et al. disclose using a shape memory polymer (SMP) (col. 3, lines 31 and 60-64) but do not disclose a photo-switchable SMP as claimed. Fine et al. require a stent that can form two stable shapes (expanded and contracted). Langer et al. disclose: (i) a material consisting essentially of at least one non-metallic photo-switchable shape memory polymer (SMP) with two light-fixable shapes in memory for use in stents (Abstract; col. 16, lines 21-26). It would have been obvious to one of ordinary skill in the art to have used the SMP of Langer et al. to construct the stent of Fine et al. because the light-induced shape change would be less invasive to surrounding tissue (col. 14, lines 16-26 of Langer et al.) and the skilled artisan would recognize the benefit of having a contracted and expanded state in memory so that deployment to the expanded state is more controlled. Fine et al. further disclose: (b) inserting the stent into a desired position (Figure 1); (c) expanding the stent to a temporary shape by means of the catheter (Figure 2; the expanded shape can be considered as temporary since the stent is intended to be collapsed after expansion - Figure 6; furthermore, the contracted state is the permanent or memorized state in Fine et al. – col. 5, lines 22-34); and (e) removing the catheter (Figure 8 – see arrow 24). It would have been obvious to one of ordinary skill in the art to have (d) irradiated the stent with light of a suitable wavelength to fix the stent in a temporary expanded shape

since the SMP of Langer et al. is intended to be fixed in a second shape after being held in that shape (col. 15, lines 9-11) and the stent of Fine et al. is intended to be forcible held in the expanded state and then cooled to fix the stent in the temporary shape (col. 5, lines 22-34). It would have been obvious to one of ordinary skill in the art to have used a catheter equipped with a suitable light source for fixing the SMP of Langer et al. since Fine et al. intend to use a catheter for fixing their SMP (col. 5, lines 22-34). Alternately, Dickson teaches that a catheter can be equipped with a suitable light source for irradiating a stent to cause shape change of an SMP (paragraph 0035). Therefore, it would have been obvious to one of ordinary skill in the art in view of Dickson to have equipped the catheter of Fine et al. with a suitable light source in order to initiate the shape change or fix the SMP of Langer et al. **Regarding clam 3**, Fine et al. disclose that the stent can be used for delivering drugs (col. 4, lines 9-11). Langer et al. disclose that that the non-shape memory material can possess an antiinflammatory active substance, an analgetic substance, an antibiotic active substance, an active substance against, an antithrombic active substance or an immunosuppressive (col. 15, line 62 to col. 16, line 5). Therefore, it would have been obvious to one of ordinary skill in the art to have incorporated at least one of these substances into the SMP of Langer et al. in order to deliver a drug to a treatment site as intended by Fine et al. **Regarding claim 4**, Langer et al. disclose that the nonmetallic SMP is selected from the group consisting of at least one of an SMP-containing polymer network (Abstract) as well as other limitations of this claim. **Regarding claim 17**, Langer et al. disclose that the SMP-containing material is selected from the group consisting of at least one of

biocompatible and haemocompatible (col. 16, lines 30-32). **Regarding claims 18-27**, Wang et al. discloses the invention substantially as claimed and described above except for the e-module of the SMP material, the reset fixation value of the SMP material, or the reset ratio of the SMP material. Langer et al. teach that it is desirable to provide SMP's for stents with the claimed properties at or near the claimed values (col. 6, lines 45-52; Table 13; Table 15 and elsewhere). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used an SMP material with the above limitations and the ranges as recited in the claims since at least some are directly taught by Langer et al. desirable for SMP's and furthermore, since it has been held that where the general conditions of a claim (as shown in Tables 13, 15 and elsewhere) are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, Applicant has not disclosed that the claimed values and ranges solve any stated problem, produce any unexpected results or are for any particular purpose other than the same purpose which the other SMP's in Applicant's disclosure serve (unless Applicant is stating that all the disclosed SMP's posses these properties in the claimed amounts). It appears that the invention would perform equally well if possessing the claimed properties in amounts outside the claimed values and ranges. Applicant has disclosed that any SMP is suitable for use with their invention (paragraph 0113 of Applicant's pre-grant publication) and has not disclosed how or why the specific materials with the claimed values and ranges would perform better for the intended use. Applicant has also disclosed that all the polymer networks of their invention (including

those disclosed as known in the prior art) have greater than 90% reset fixation values (paragraph 0147 of Applicant's pre-grant publication). Therefore, it would have been an obvious matter of design choice to use SMP's with these values and ranges in constructing the stent of Wang et al. **Regarding claim 28**, Langer et al. disclose that the SMP comprises at least one of caprolacton units, pentadecalacton units, ethyleneglycol units, propyleneglycol units, lactic acid units, glycol acid units and combinations thereof (col. 7, line 36 to col. 8, line 30). **Regarding claim 29**, Langer et al. disclose that an SMP can be made from cross-linked caprolactonemacromonomers (col. 4, lines 42-45). **Regarding claim 30**, Langer et al. disclose that the SMP can be formed into articles using one from the group consisting of being extruded, coated, casted, spinned, weaved and combinations thereof (col. 3, lines 41-45). Fine et al. disclose that the stent can be molded (col. 3, lines 60-64). Therefore, it would have been obvious to one of ordinary skill in the art to have used one of the methods of Langer et al. to produce the stent of Fine et al. **Regarding claim 35**, in addition to the limitations already addressed above, Fine et al. in view of Langer et al. or Langer et al. and Dickson disclose: (b) expanding the balloon to produce a direct contact with the stent; (d) relieving the balloon thereby fixing the contracting stent on the balloon; and (e) removing the catheter with the stent. (col. 4, line 41 to col. 5, line 34 of Fine et al.). Regarding step (c), Fine et al. disclose heating the stent to activate the shape memory effect and recovery of the permanent compressed shape of the stent (col. 5, lines 22-34). Langer et al. disclose irradiating the stent to effect shape change as described above. Langer et al. further disclose that the SMP can be moved between either shape

(col. 14, lines 55-63; col. 15,lines 15-33). Therefore, it would have been obvious to one of ordinary skill in the art to have irradiated the stent of Fine et al. containing the SMP of Langer et al. in order to recover the compressed shape. **Regarding claims 38-40**, these limitations have been addressed above. **Regarding claim 46**, Langer et al. disclose that the light of a suitable wavelength is selected from IR irradiation, NIR irradiation, and UV irradiation (col. 14, lines 2-26).

Response to Arguments

5. Applicant's arguments with respect to the pending claims have been considered but are either moot in view of the new ground(s) of rejection or are not persuasive. Applicant has argued that Langer et al. do not disclose using a photo-switchable SMP as a stent material. Langer et al. effectively disclose that any of their SMP's can be used to produce a stent as cited above. As acknowledged by Applicant, Langer et al. do disclose photo-switchable SMP's in general. Therefore, a stent constructed from a photo-switchable SMP is effectively anticipated by Langer et al.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas McEvoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
3/24/11